

### § 84.3

*Respirators for escape only* means respiratory devices providing protection only during escape from hazardous atmospheres.

*(Single-use respirator)* means a respirator that is entirely discarded after excessive resistance, sorbent exhaustion, or physical damage renders it unsuitable for further use.

*Vapor* means the gaseous state of a substance that is solid or liquid at ordinary temperature and pressure.

[60 FR 30355, June 8, 1995, as amended at 80 FR 3906, Jan. 26, 2015]

### § 84.3 Respirators for mine rescue or other emergency use in mines.

(a)(1) NIOSH and the Mine Safety and Health Administration (MSHA), U.S. Department of Labor, shall jointly review and issue certifications for respirators used for mine emergencies and mine rescue, including any associated service-life plans, users' manuals and other supporting documentation.

(2) Each certification for a respirator designed for mine rescue or other emergency use in mines shall include, as a condition of approval, any use limitations related to mine safety and health.

(b) NIOSH and MSHA shall jointly determine appropriate recall and retrofit remedies for field complaints or identified deficiencies involving any respirators used in the mining environment.

## Subpart B—Application for Approval

### § 84.10 Application procedures.

(a) Inspection, examination, and testing leading to the approval of the types of respirators classified in subpart F of this part shall be undertaken by the Institute only pursuant to written applications which meet the minimum requirements set forth in this subpart B.

(b) Applications must be submitted in accordance with the *Standard Application Procedure for the Certification of Respirators under 42 CFR 84*, (*Standard Application Procedure*) available on the NPPTL Web site, to Records Room, National Personal Protective Technology Laboratory, P.O. Box 18070, 626 Cochran's Mill Road, Pittsburgh, PA 15236.

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(c) Except as provided in § 84.64, the examination, inspection, and testing of all respirators will be conducted or caused to be conducted by the National Personal Protective Technology Laboratory.

(d) Applicants, manufacturers, or their representatives may visit or communicate with the National Personal Protective Technology Laboratory in order to discuss the requirements for approval of any respirator or the proposed designs thereof. No charge will be made for such consultation and no written report will be issued to applicants, manufacturers, or their representatives by the Institute as a result of such consultation.

(e) Respirators having electrical or electronic components that are required to be permissible under chapter I of title 30 shall be tested in accordance with 30 CFR part 18. Applications for approval of such respirators by MSHA shall be submitted in writing to: MSHA, Approval and Certification Center, Box 251, Industrial Park Road, Triadelphia, West Virginia 26059.

[60 FR 30355, June 8, 1995, as amended at 80 FR 3906, Jan. 26, 2015]

### § 84.11 Contents of application.

(a) Each application for approval shall contain a complete written description of the respirator for which approval is requested together with drawings and specifications (and lists thereof) showing full details of construction of the respirator and of the materials used.

(b) Drawings shall be titled, numbered, and dated; any revision dates shall be shown on the drawings, and the purpose of each revision being sought shall be shown on the drawing or described on an attachment to the drawing to which it applies.

(c) Each application for approval shall contain a proposed plan for quality control which meets the minimum requirements set forth in subpart E of this part.

(d) Each application shall contain a statement that the respirator has been pretested by the applicant as prescribed in § 84.64, and shall include the results of such tests.

(e) Each application for approval shall contain a statement that the respirator and component parts submitted for approval are either prototypes, or made on regular production tooling, with no operation included which will not be incorporated in regular production processing.

(The information collections contained in this section are approved under OMB control number 0920-0109)

**§ 84.12 Delivery of respirators and components by applicant; requirements.**

(a) Each applicant shall, when an application is filed pursuant to § 84.10, be advised by the Institute of the total number of respirators and component parts required for testing.

(b) The applicant will deliver, at his or her own expense, the number of completely assembled respirators and component parts required for their examination, inspection, and testing, to the National Personal Protective Technology Laboratory.

(c) Respirators and component parts submitted for approval must be made from materials specified in the application.

(d) One completely assembled respirator approved under the provisions of this part may be retained by the Institute as a laboratory exhibit, the remaining respirators may be returned to the applicant at his own expense, upon written request within 30 days after notice of approval. If no such request is made, the respirators will be disposed of by the Institute in such manner as it deems appropriate.

(e) Where a respirator fails to meet the requirements for approval set forth in this part, all respirators and components delivered in accordance with this section may be returned to the applicant at his own expense, upon written request within 30 days after notice of disapproval. If no such request is made, the respirators will be disposed of by the Institute in such manner as it deems appropriate.

[60 FR 30355, June 8, 1995, as amended at 80 FR 3906, Jan. 26, 2015]

**Subpart C—Fees**

SOURCE: 80 FR 3906, Jan. 26, 2015, unless otherwise noted.

**§ 84.20 Establishment of fees.**

(a) This section establishes a system under which NIOSH charges a fee for services provided to applicants for conformity assessment activities conducted by NIOSH for respiratory protective devices under 42 CFR part 84. This section specifies the purposes for which fees will be assessed and the cost factors for such assessments.

(b) Fees will be charged for:

(1) *Respirator certification application, approval, approval modification, records maintenance, and testing.* Application processing under this Part by engineers, technicians and other specialists, including administrative review of applications, analysis of drawings, technical evaluation, testing, test set up and tear down, and consultation on applications, clerical services, computer tracking and status reporting, records control and security, and document preparation directly supporting application processing. This fee also contributes to a proportionate share of management, administration and operation of the NIOSH National Personal Protective Technology Laboratory;

(2) *Maintenance of testing and approval facilities and test equipment.* Amortization of facility improvements and depreciation of buildings and equipment used for testing and evaluation or otherwise directly associated with application processing;

(3) *Site qualification.* Initial review and approval, as specified under 42 CFR part 84 subpart E—Quality Control, of manufacturing facilities that may be used to manufacture respirators, principal components, and/or subassemblies;

(4) *Quality assurance maintenance.* Quality site audits to verify conformance to the requirements of §§ 84.33, 84.40, 84.41, 84.42, 84.43; and

(5) *Maintenance of product performance.* Product audits to verify the performance of commercially available respirators which have been granted a NIOSH certificate of approval.

(c) Fees will not be charged for: